

15090728

7. 510(k) Summary

APR 16 2009

Applicant:

Micro Therapeutics, Inc., dba ev3 Neurovascular
9775 Toledo Way
Irvine, CA 92618
USA
Phone: 949.680.1293
Fax: 949.859.7228

Date:

March 16, 2009

Contact Person:

Jason K. Lyon
Manager, Regulatory Affairs

Proprietary Device Name:

HyperGlide™ Occlusion Balloon System

Common Device Name:

Occlusion Balloon Catheter
(21 CFR 870.4450, Product Code MJN)

Classification:

Class II

Predicate Devices:

Micro Therapeutics, Inc. Equinox™ Occlusion
Balloon Catheter (later changed to HyperGlide™)
cleared under K011526.
Micro Therapeutics, Inc., HyperGlide™ Occlusion
Balloon System
cleared under K021066

Manufacturer:

Micro Therapeutics, Inc., ev3 Neurovascular a
division of ev3, Inc.
9775 Toledo Way
Irvine, CA 92618
USA

7.1 Substantially Equivalent To:

The HyperGlide™ Occlusion Balloon (5mm version) is substantially equivalent to the HyperGlide™ Occlusion Balloon family (4mm version) and the HyperForm™ Occlusion Balloon System (7mm version) in that the intended use, design,

specifications, and materials are the same. The HyperGlide™ Occlusion Balloon (5mm version) is affixed (thermally bonded) to the same catheter size 2.8F proximal and 2.2F distal as the cleared HyperGlide™ Occlusion Balloon (4mm version). The methods, materials in construction, packaging, and sterilization are the same as the predicate versions. Furthermore, the Indications For Use is identical and does not alter the fundamental scientific technology of the HyperGlide™ Occlusion Balloon System. A summary of equivalency is below. (See Section 11 and ATTACHMENT 3 for DVT Test Report and Balloon Data).

7.2 *Description of the Device Subject to Premarket Notification:*

The HyperGlide™ Occlusion Balloon System is a single lumen, open-ended balloon catheter designed for advancement into the vasculature over a .010" guidewire. Balloon inflation is accomplished by advancement of the guidewire through the open distal end, redirecting inflation media to the balloon through side-holes in the catheter wall. The HyperGlide™ Occlusion Balloon System is currently cleared for commercial distribution for sizes 4x10, 4x15, 4x20, and 4x30. The HyperGlide™ Occlusion Balloon System is packaged with a .010" X-pedian™ hydrophilic guidewire, manufactured by Micro Therapeutics, Inc., d/b/a ev3 Neurovascular and cleared under K982543. The device is sold and packaged with a .010" guidewire in a sterile pouch and for single use only.

7.3 *Indications For Use:*

The HyperGlide™ Occlusion Balloon System is indicated for use in the blood vessels of the peripheral and neurovasculature where temporary occlusion is desired. The HyperGlide™ Occlusion Balloon System offers a vessel selective technique of temporary vascular occlusion which is useful in selectively stopping or controlling blood flow.

7.4 *Performance Data:*

The HyperGlide™ Occlusion Balloon System was verified and tested according to performance testing standards ISO 10555 Sterile, Single Use Intravascular Catheters – Parts 1 and 4. These tests include dimensional verification, balloon fatigue, catheter tensile strength, torque strength, flexibility, burst testing, and so on. The test results demonstrated in this submission meet or exceed the requirements of these standards and prove that the subject device of this submission is substantially equivalent to the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 16 2009

Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
c/o Mr. Jason K. Lyon
Manager, Regulatory Affairs
9775 Toledo Way
Irvine, CA 92618

Re: K090728

Trade/Device Name: HyperGlide Occlusion Balloon System

Regulation Number: 21 CFR 870.4450

Regulation Name: Vascular Clamp

Regulatory Class: Class II (two)

Product Code: MJN

Dated: March 18, 2009

Received: March 19, 2009

Dear Mr. Lyon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

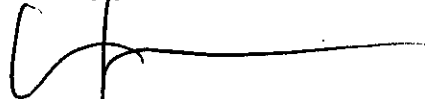
Page 2 – Mr. Jason K. Lyon

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

6. Statement of Indications for Use

Indications for Use

510(k) Number (if known):

K090728

Device Name: HyperGlide Occlusion Balloon System

Indications For Use:

The HyperGlide™ Occlusion Balloon System is indicated for use in the blood vessels of the peripheral and neuro vasculature where temporary occlusion is desired. The HyperGlide™ Occlusion Balloon offers a vessel selective technique of temporary vascular occlusion, which is useful in selectively stopping or controlling blood flow.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K090728

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